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Amendment and Correction of Previous Statements
Attorney Docket No.: S63.2-6748-US03

CORRECTIONS OF PREVIOUS STATEMENTS

On page 10 of applicants' 5/4/2006 "Response and Supplement to Request for Interference," it was stated that claims 86-89 correspond to the count because they are anticipated or obvious variants of the subject matter of the count. On reconsideration applicants believe this to be incorrect as to claim 88. The two-sleeve species of claim 88 is not anticipated by the proposed count and is not believed to be obvious when the count is taken with the prior art to the applicant's invention. Therefore the statement of unpatentability of claim 88 in view of the count is expressly withdrawn.

This correction is believed to necessitate a second count in the proposed interference with Berthiaume et al, US 6,110,146. The second count is proposed in Appendix A together with a proposed designation of claims corresponding to each of the two proposed counts in accordance with 37 CFR 41.202(a)(3).

Appendix B provides the claim chart required under 37 CFR 41.202(a)(3) for the two proposed counts.

Appendix C provides the detailed explanation why applicants will prevail on priority on each of the two proposed counts for each of counts as required in 37 CFR 41.202(a)(4).

Appendix D provides the written description claim chart for the copied claims as required in 37 CFR 41.202(a)(5).

Appendix E provides a chart showing constructive reduction to practice in each of the applications for which benefit is sought of the subject matter of the two proposed counts as required in 37 CFR 41.202(a)(6).

Additionally applicants have discovered that the claim chart on pages 12-14 of applicants' 5/4/2006 "Response and Supplement to Request for Interference" contained a number of errors, in particular reliance on Figs 46-56 for constructive reduction to practice of the invention of the count. Figures 46-56 are not embodiments of the count (now proposed count 1).

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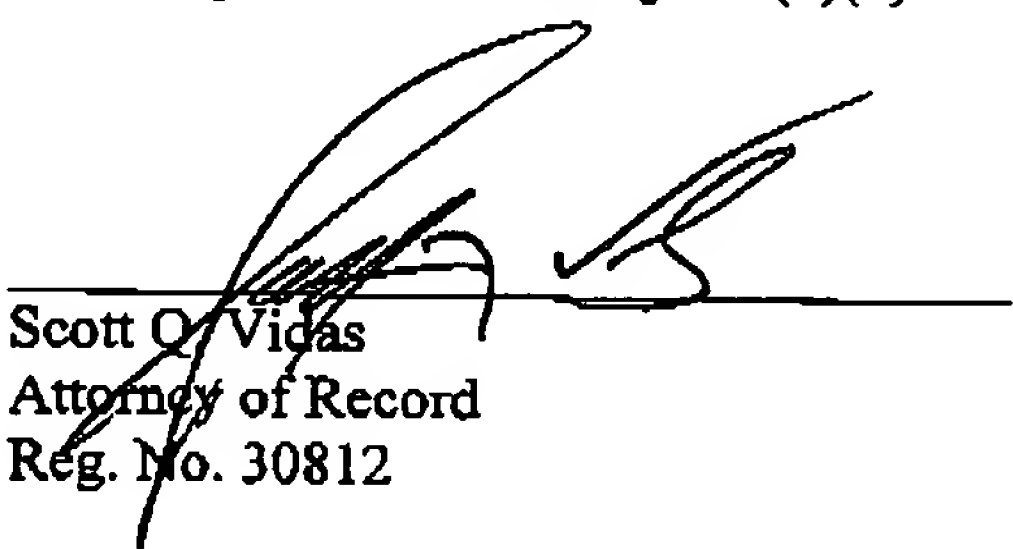
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The previous written description chart is hereby expressly withdrawn. Corrected information is provided in the claim charts of Appendices D and E.

Further, applicants have decided that the "elastomeric material" subject matter of claim 89 is suggested in the specification, express written description support will not be asserted. Accordingly claim 89 has been cancelled.

Finally the course of preparing this paper the issue of inventorship was reexamined. It was determined that the Preliminary Amendment filed with this application, cancelling the original claims and submitting copied claims should have been accompanied with a change in inventorship since the subject matter of the copied claims was invented by less than all of the originally named inventors. That amendment has been provided hereinabove, together with the acknowledgment required in 37 CFR §1.48(b)(1). Please charge the Processing Fee in the amount of \$130.00, under 37 CFR §1.17(i), as required in 37 CFR §1.48(b)(2) to our Deposit Account No. 22-0350



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Appendix A

Proposed Counts, Designation of Claims and Showing of How
Designated Claims Correspond to the Count

(37 CFR §41.202(a)(2))

Two counts are now proposed by applicants Homan et al for the interference with Berthiaume et al, US 6,110,476. The counts are related as a genus (count 1) and a species (count 2). The species are seen to be patentably distinct on the basis that at least as of Applicants priority application date of March 5, 1997, the subject matter of the species count would not have been obvious from the genus count 1. In particular the use of a second sleeve in the balloon protector of count 2 two-sleeve balloon protector is not *prima facie* obvious from the slit sleeve balloon protector recited in count 1. Accordingly the proposed counts are amended as follows:

Count 1: A protective sleeve for a balloon dilatation catheter comprising:
an elongate tubular member having a neck portion and a slit extending along the entire length of the tubular member from a proximal end to a distal end thereof, wherein a distal portion of the tubular member is flared from the neck portion to the distal end of the tubular member to define an enlarged funnel-like opening.

The claims proposed to be designated as corresponding to Count 1 are Homan et al, claims 85-87 and Berthiaume et al claims 1-7. The rationale is provided in Table 1 below.

Count 2: A protective sleeve as defined in count 1 further comprising:
an outer sleeve disposed about those portions of the tubular member proximal of the flared distal portion, the outer sleeve being configured to maintain the slit of the tubular member in a closed configuration.

The claims proposed to be designated as corresponding to Count 2 are Homan et al, claim 88 and Berthiaume et al claim 4. The rationale is provided in Table 1 below. Note that

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due to the fact that Applicant's priority patent US 5,893,868, which issued from application 08/812,351, filed March 5, 1997, is prior art to each of Berthiaume et al's claims under 35 USC 102(e), whereas US 5,893,868 is not prior art to applicants, Berthiaume et al's claim 4 is designated as corresponding to both counts whereas Homan et al's claim 88 is only designated as corresponding to Count 2.

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Table 1 Basis for Designation of claims corresponding to Count 1		
Homan et al.		Rationale
85. A protective sleeve for a balloon dilatation catheter comprising: an elongate tubular member having a neck portion and a slit extending along the entire length of the tubular member from a proximal end to a distal end thereof, wherein a distal portion of the tubular member is flared from the neck portion to the distal end of the tubular member to define an enlarged funnel-like opening.		The claim is Count 1 and therefore stands or falls with the count.
86. A protective sleeve as defined in claim 85, wherein the slit extends along a plane that includes a longitudinal axis of the tubular member.		A skilled person would know from the recitation in Count 1 of "a slit extending along the entire length of the tubular member from a proximal end to a distal end thereof," that the slit could run along the length in a shortest length straight line which would put the slit in a plane that includes the longitudinal axis of the tubular member. Therefore the subject matter is obvious from Count 1.
87. A protective sleeve as defined in claim 85 wherein the slit is helical.		A skilled person would know from the recitation in Count 1 of "a slit extending along the entire length of the tubular member from a proximal end to a distal end thereof," that the slit could run along the length in an angular manner relative to the longitudinal axis, which produces a helix. Therefore the subject matter is obvious from Count 1.
Berthelme et al		
1. A protective sleeve for a balloon dilatation catheter comprising: an elongate tubular member having a neck portion and a slit extending along the entire length of the tubular member from a proximal end to a distal end thereof, wherein a distal portion of the tubular member is flared from the		The claim is the Count 1 and therefore stands or falls with the count.

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neck portion to the distal end of the tubular member to define an enlarged funnel-like opening.	
2. A protective sleeve as defined in claim 1, wherein the slit extends along a plane that includes a longitudinal axis of the tubular member.	<p>A skilled person would know from the recitation in Count 1 of "a slit extending along the entire length of the tubular member from a proximal end to a distal end thereof," that the slit could run along the length in a shortest length straight line which would put the slit in a plane that includes the longitudinal axis of the tubular member. Therefore the subject matter is obvious from Count 1.</p> <p>Furthermore, a longitudinal slit is shown in Fig. 8 of US 5,893,868 which is prior art to Berthiaume et al under 35 USC § 102(e). Therefore the claim is anticipated if Berthiaume et al is not entitled to Count 1.</p>
3. A protective sleeve as defined in claim 1 wherein the slit is helical.	<p>A skilled person would know from the recitation in Count 1 of "a slit extending along the entire length of the tubular member from a proximal end to a distal end thereof," that the slit could run along the length in an angular manner relative to the longitudinal axis, which produces a helix. Therefore the subject matter is obvious from Count 1.</p> <p>Furthermore, helical slits are shown in Figs. 9b - 9e, 9g and 9i of US 5,893,868. Therefore the claim is anticipated if Berthiaume et al is not entitled to Count 1.</p>
4. A protective sleeve as defined in claim 1 further comprising: an outer sleeve disposed about those portions of the tubular member proximal of the flared distal portion, the outer sleeve being configured to maintain the slit of the tubular member in a closed configuration.	<p>Use of a spiral sleeve 66, e.g. as in any of Figs. 9a - 9h, as an inner sleeve with an outer sleeve disposed thereabout is taught at col. 8, lines 2-5 of US 5,893,868. The outer sleeve exerts closing force on the slit of the inner sleeve. See col. 9, lines 10-18 of US 5,893,868. Therefore the claim is anticipated if Berthiaume et al is not entitled to Count 1.</p>
5. A protective sleeve as defined in claim 4 wherein the outer sleeve is elastomeric.	<p>US 5,893,868 teaches that the outer sleeve is flexible, applies compressive force on the inner sleeve and may be made of polymer material:</p> <p>"The second removable (outer) sleeve is positioned over the first (inner) sleeve, the outer sleeve having a constrictive relationship with the inner</p>

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	<p>sleeve. The outer sleeve thereby provides an additional compressive force to reduce the profile of the constricted balloon." (col.2, lines 43-45.)</p> <p>"A preferred material for this balloon protector is LDPE. The spiral sleeve provides a device with a compressive force that has flexibility to conform to diameter changes of a collapsed balloon." (col. 7, line 65 - col. 8, line 2)</p> <p>A skilled person would recognize that a polymeric material with a high range of elastic response would be a suitable material for providing the compressive and flexibility properties taught for the protective sleeve. Elastomeric materials have a high range of flexibility and elastic response, and therefore the use of an elastomeric material would have been obvious as an alternative polymer to LDPE.</p> <p>Therefore the claim is obvious if Berthiaume et al is not entitled to Count 1.</p>
<p>6. A balloon catheter and a protective sleeve for the balloon of the catheter comprising, in combination:</p> <p>a catheter having a shaft and a balloon mounted thereon, wherein the shaft has a distal tip portion that extends distally beyond a distal extremity of the balloon; and</p> <p>a protective sleeve as defined in claim 1, wherein a proximal portion of the sleeve is disposed about and encloses the balloon, the sleeve being mounted on the catheter to locate the distal tip portion of the catheter at the narrowest portion of the funnel defined by the flared distal portion of the tubular member whereby a guidewire backloaded through the flared distal portion will be guided into registry with the distal tip of the catheter shaft.</p>	<p>The combination of balloon catheter and protective sleeve are shown in Figs. 1 and 43 of US 5,893,868. The outer protective sleeve extends beyond a distal extremity of the balloons, as is better seen in Figs. 2 and 45, respectively.</p> <p>The use spiral sleeve 66, as an outer sleeve is taught at col. 8, lines 2-5 of US 5,893,868. Use of any of the sleeves 66 of Figs. 9b - 9e or 9g in this way meets the remaining recitations of this claim. Note that US 5,893,868 teaches that the configuration of Fig. 8 with flared proximal and distal ends "allows a doctor to prep and introduce the guide wire into the catheter without touching the balloon" (col. 7, lines 41-50).</p> <p>Therefore the claim is anticipated if Berthiaume et al is not entitled to Count 1.</p>
<p>7. A method for backloading a guidewire into a balloon dilatation catheter comprising:</p>	<p>US 5,893,868 teaches providing a protective sleeve as in claim 1, as previously shown, as well placing the sleeve about the balloon, with the balloon having been preliminary wrapped to a low profile configuration. See e.g. col. 6, lines</p>

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<p>providing a protective sleeve as defined in claim 1;</p> <p>placing a proximal portion of the protective sleeve about the balloon of the catheter, with the balloon having been preliminarily wrapped to a low profile configuration;</p> <p>positioning a distal tip of the catheter at the apex of the funnel-like opening; and</p> <p>backloading a proximal end of the guidewire through the funnel-like opening into a distal orifice of the catheter.</p>	<p>47-59, col. 8, lines 30-35; col. 9, lines 25-30.</p> <p>Berthiaume US 6,110,146, in the Background section admits that backloading of guidewires was conventional:</p> <p>A common technique for loading the guidewire into the guidewire lumen of the catheter is to "backload" the guidewire, that is, to insert the proximal end of the guidewire into the distal outlet orifice at the distal tip of the catheter. The guidewire then is fed proximally through the guidewire lumen until the proximal end of the guidewire emerges from the proximal end of the catheter. Backloading the guidewire into the distal end of the guidewire lumen of the catheter is the only practical way to advance a catheter onto the guidewire that is already in place in the patient, as may occur when the original catheter is to be exchanged with another catheter.</p> <p>(col. 2, lines 1-13)</p> <p>Because backloading was conventional it would have been obvious to backload a guidewire onto the catheters of US 5,893,868. Therefore the claim is obvious if Berthiaume et al is not entitled to Count 1.</p>
<p>8. A method as defined in claim 7 further comprising:</p> <p>sliding the protective sleeve distally off of a distal end of the catheter and onto the guidewire; and</p> <p>removing the protective sleeve from the guidewire by passing the guidewire transversely through the slit.</p>	<p>US 5,893,868 teaches that the inner and outer sleeves may be made of low friction material, such as PTFE, which will not stick to the catheter or balloon (col. 6, lines 41-44).</p> <p>When the protective sleeve is made of PTFE and has a longitudinal slit as in Fig. 8, sliding the sleeve off of the balloon and passing the guidewire through the slit would be an obvious alternative to removing by banana peel removal since the sleeve does not stick to the balloon. Therefore the claim is obvious if Berthiaume et al is not entitled to Count 1.</p>
<p>9. A method as defined in claim 7 further comprising:</p> <p>applying a constriction about the protective sleeve to maintain the slit in its closed configuration;</p> <p>removing the constriction before backloading the guidewire into the catheter.</p>	<p>Use of an outer sleeve as taught in US 5,893,868 meets the constriction recitation of this claim, (see discussion of claim 4). Removal of the inner and outer sleeves prior to introduction of the catheter into the vasculature is taught at col. 9, lines 45-48.</p> <p>For a two sleeve embodiment, removal of the outer sleeve before or after backloading of a guidewire into the catheter would have been an obvious option</p>

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to the skilled surgeon. If the outer sleeve is removed the inner sleeve can still be left in place and protect the balloon during backloading of the catheter. Therefore the claim is obvious if Berthiaume et al is not entitled to Count 1.

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Table 2 Basis for Designation of Claims Corresponding to Count 2		
Homan et al.		Rationale
88. A protective sleeve as defined in claim 85 further comprising: an outer sleeve disposed about those portions of the tubular member proximal of the flared distal portion, the outer sleeve being configured to maintain the slit of the tubular member in a closed configuration.		The claim is Count 2 and therefore stands or falls with the count.
Berthelme et al		
4. A protective sleeve as defined in claim 1 further comprising: an outer sleeve disposed about those portions of the tubular member proximal of the flared distal portion, the outer sleeve being configured to maintain the slit of the tubular member in a closed configuration.		The claim is Count 2 and therefore stands or falls with the count.

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Appendix B
Interfering subject Matter Claim Chart
(37CFR §41.202(a)(3))

At least one claim of each party corresponds to the count and interferes because each party has at least one claim which is the same as each count and cannot be patentable if the count is awarded to the other party. Table 3 provides the requisite claim chart.

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Table 3
Claim Chart Showing Interfering Subject Matter

Count 1	Berthiaume U.S. 6,110,146	Holman U.S. Application 09/737,118	Interfering Subject Matter
A protective sleeve for a balloon dilatation catheter comprising: an elongate tubular member having a neck portion and a slit extending along the entire length of the tubular member from a proximal end to a distal end thereof, wherein a distal portion of the tubular member is flared from the neck portion to the distal end of the tubular member to define an enlarged funnel-like opening.	1. A protective sleeve for a balloon dilatation catheter comprising: an elongate member having a neck portion and a slit extending along the entire length of the tubular member from a proximal end to a distal end thereof, wherein a distal portion of the tubular member is flared from the neck portion to the distal end of the tubular member to define an enlarged funnel-like opening.	85. A protective sleeve for a balloon dilatation catheter comprising: an elongate member having a neck portion and a slit extending along the entire length of the tubular member from a proximal end to a distal end thereof, wherein a distal portion of the tubular member is flared from the neck portion to the distal end of the tubular member to define an enlarged funnel-like opening.	The claims are identical to each other and to the Count. The two-way unpatentability test under 37 C.F.R. § 41.203(a) is satisfied on the basis that both the Berthiaume '146 patent and the Holman '118 application have a claim identical to the proposed count.
Count 2	Berthiaume U.S. 6,110,146	Holman U.S. Application 09/737,118	Interfering Subject Matter
A protective sleeve as defined in count 1 further comprising: an outer sleeve disposed about those portions of the tubular member proximal of the flared distal portion, the outer sleeve being configured to maintain the slit of the tubular member in a closed configuration.	4. A protective sleeve as defined in claim 1 further comprising: an outer sleeve disposed about those portions of the tubular member proximal of the flared distal portion, the outer sleeve being configured to maintain the slit of the tubular member in a closed configuration.	88. A protective sleeve as defined in claim 85 further comprising: an outer sleeve disposed about those portions of the tubular member proximal of the flared distal portion, the outer sleeve being configured to maintain the slit of the tubular member in a closed configuration.	The claims are identical to each other and to the Count. The two-way unpatentability test under 37 C.F.R. § 41.203(a) is satisfied on the basis that both the Berthiaume '146 patent and the Holman '118 application have a claim identical to the proposed count.

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Appendix C

Detailed Explanation Why Applicants Will Prevail On Priority
(37 C.F.R. § 41.202(a)(4))

Applicants are entitled to a constructive reduction to practice for each of the counts in each of the following applications:

U.S. Application No. 09/737,118, filed December 14, 2000, the present application, on the basis that the counts are supported as shown in Appendix E.

U.S. Application No. 09/528,613 filed March 20, 2000 of Holman et al., now US Patent 6,416,529, on the basis that the present application is a continuation of 09/528,613 and the counts are supported as shown in Appendix E;

U.S. Application No. 09/034,434 filed March 4, 1998 of Holman et al, now US patent 6,152,944, on the basis that application 09/528,613 is a division of application 09/034,434, priority is claimed in the present application and the counts are supported as shown in Appendix E; and

U.S. Application No. 08/812,351 filed March 5, 1997 of Hanson et al., now U.S. patent 5,893,868, on the basis that application 09/034,434 is a continuation-in-part of application 08/812,351, priority is claimed in the present application, and the counts are supported in Appendix E.

Applications 09/034,434 and 08/812,351 are both prior to Berthiaume et al's September 30, 1998 filing date. Applicants therefore are the Senior Party as to both counts and are *prima facie* entitled to prevail on priority for both counts. Further, Applicants are entitled to an invention date earlier than March 5, 1997, based upon at least a conception prior to that date.

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Appendix D
Written Description Claim Chart
(37 CFR 41.202 (a)(5))

Table 4 identifies locations of written description support in the present application for applicants' claims.

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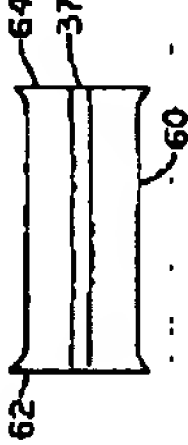
Table 4 Written Description Support for Each Claim in Homan et al's Specification		
Claim	Homan et al, Application 09/737,118, filed 12/14/2000	
85. A protective sleeve for a balloon dilatation catheter comprising: an elongate member having a neck portion and a slit extending along the entire length of the tubular member from a proximal end to a distal end thereof, wherein a distal portion of the tubular member is flared from the neck portion to the distal end of the tubular member to define an enlarged funnel-like opening.	<p>The subject matter is shown in Figure 8, Figures 9b-9e, 9g and 9i, and the descriptive disclosure in the specification:</p> <p>Fig. 8</p>  <p>"Referring to FIG. 8, an inner sleeve, outer sleeve or singular sleeve balloon protector of the present invention may also be provided in the form of a polymeric tube 60 with flared proximal end 62, flared distal end 64 and a longitudinal slit 37. This inventive balloon protector is unique in that the balloon protector can be removed from the catheter after the catheter has been prepped and loaded onto a guide wire. This allows the balloon protector to be peeled off the shaft, like peeling a banana. Such a construction allows a doctor to prep and introduce the guide wire into the catheter without touching the balloon." (page 13, line 28 - page 14, line 4)</p>	

Fig. 9b

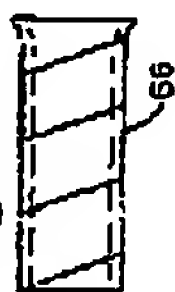


Fig. 9c

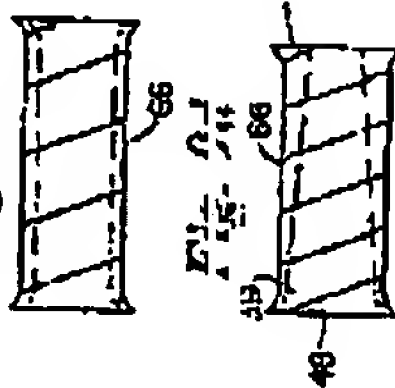


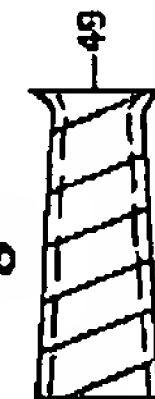
Fig. 9e



Fig. 9g



Fig. 9i



"A balloon protector according to the present invention may be a spiral sleeve 66 made of a polymeric material or a metal ribbon. It can also be formed by spiral cutting a tube to be the balloon protector, in a configuration as shown in FIGS. 9a-h and j and as shown at FIGS. 4a-b. This balloon protector conforms to diameter changes throughout the length of the collapsed balloon, and in a preferred embodiment has a pre-mounted inner diameter

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	<p>which is less than the outer diameter of the collapsed balloon to provide radial compression when applied on the balloon. The radial strength of the spiral sleeve is related to the material of which the sleeve is made, the pitch of the spiral, the wall thickness of the sleeve and the inner diameter of the sleeve. A preferred material for this balloon protector is LDPE. The spiral sleeve provides a device with a compressive force that has flexibility to conform to diameter changes of a collapsed balloon (a balloon which when expanded has a non-uniform diameter). The spiral sleeve 66 may be used alone as a single balloon protector, or as an inner sleeve with any suitable outer sleeve, for example, a sleeve with a longitudinal slit as shown at FIGS. 3 and 8. The spiral sleeve 66 may also be used as an outer sleeve with any suitable inner sleeve, for example, a sleeve with a longitudinal slit as shown at FIGS. 3 and 8.</p> <p>"FIGS. 9a-i and j show alternative embodiments of a spiral sleeve according to the present invention. FIG. 9a and 9b show a spiral sleeve with a flare at one end, FIG. 9a showing a spiral sleeve with a proximal flare 48, and FIG. 9b showing a distal flare 49. FIG. 9c shows a spiral sleeve 66 with proximal and distal flares 48,49. Prior to use (in a premounted state) the spiral sleeves shown in FIGS. 9a-c have a substantially uniform outer diameter, inner diameter and wall thickness. FIG. 9d shows a spiral sleeve with proximal and distal flares 48,49. FIG. 9e shows a spiral sleeve with a distal flare. FIG. 9f shows a spiral sleeve with a proximal flare. Prior to use (in a premounted state) the spiral sleeves shown in FIGS. 9d-f have a substantially uniform outer diameter, a non-uniform, tapered inner diameter and a non-uniform wall thickness. FIG. 9g shows a spiral sleeve with proximal and distal flares 48,49. FIG. 9h shows a spiral sleeve with a proximal flare 48. FIG. 9j shows a spiral sleeve with a distal flare 49. Prior to use (in a premounted state) FIGS. 9g, h and j have a non-uniform tapered inner and outer diameter, and a substantially uniform wall thickness."</p> <p>(page 14, line 5-page 15, line 3)</p>
86. A protective sleeve as defined in claim 85, wherein the slit extends along a plane that includes a longitudinal axis of the tubular member.	Figure 8 and page 13, lines 28-31.
87. A protective sleeve as defined in claim 85 wherein the slit is helical.	Helical slits are shown in Figs. 9b - 9e, 9g and 9i.

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88. A protective sleeve as defined in claim 85 further comprising:
an outer sleeve disposed about those portions of the tubular
member proximal of the flared distal portion, the outer sleeve
being configured to maintain the slit of the tubular member in a
closed configuration.

Figures 2 and 5 show inner and outer sleeves. See also page 9, lines 26-30.
Fig. 8, is disclosed as "an inner sleeve, outer sleeve or singular sleeve balloon protector
of the present invention" at page 12, lines 7-11.

Page 3, lines 22-25: "The second removable (outer) sleeve is positioned over the first
(inner) sleeve, the outer sleeve having a constrictive relationship with the inner sleeve. The
outer sleeve thereby provides an additional compressive force to reduce the profile of the
constricted balloon."

Page 16, lines 5-10: "Prior to placement of sleeves 28 and 40 on the catheter, outer
sleeve 40 has an inner diameter less than the outer diameter of the inner sleeve 28. In a
preferred embodiment, the inner diameter of outer protector sleeve 40 slightly smaller
(about 0.001 inch smaller, for example) than the outer diameter of inner protector sleeve
28. This causes slit 36 to be closed when outer protector sleeve 40 is applied over inner
protector sleeve 28, in addition to overall compression of inner protective sleeve 28."

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Appendix E
Constructive Reduction to Practice Claim Chart
(37 CFR 41.202 (a)(6))

Request to be Accorded Benefit of Prior Applications

Applicants hereby formally request that in the declaration of the interference they be accorded benefit of the filing date of the following prior applications:

U.S. Application No. 09/737,118, filed December 14, 2000, the present application, on the basis of written description support as shown in Appendix B.

U.S. Application No. 09/528,613 filed March 20, 2000 of Holman et al., now US Patent 6,416,529, on the basis that the present application is a continuation of 09/528,613 and written description support as shown in Appendix B;


U.S. Application No. 09/034,434 filed March 4, 1998 of Holman et al, now US patent 6,152,944, on the basis that application 09/528,613 is a division of application 09/034,434 and written description support as shown in Appendix B; and

U.S. Application No. 08/812,351 filed March 5, 1997 of Hanson et al., now U.S. patent 5,893,868, on the basis that application 09/034,434 is a continuation-in-part of application 08/812,351 and written description support as shown in Appendix B.

Table 4 identifies locations of disclosure providing constructive reduction to practice of the subject matter of the counts for each application for which applicant requests benefit.

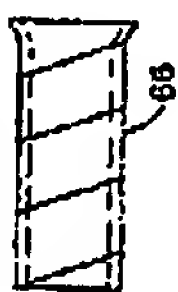
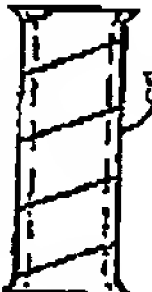
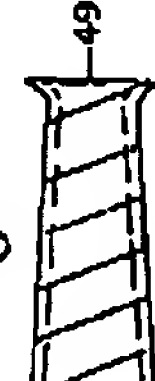
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Table 4 Constructive Reduction to Practice of the Subject Matter of the Proposed Counts				
Count	Application 08/812,351, filed March 5, 1997 US 5893868	Application 09/034,434, filed March 4, 1998 US 6,152,944	Application 09/528,613, filed 03/20/2000 US 6,416,529	Application 09/737,118, filed 12/14/2000 (Current application)
1 A protective sleeve for a balloon dilatation catheter comprising: an elongate member having a neck portion and a slit extending along the entire length of the tubular member from a proximal end to a distal end thereof, wherein a distal portion of the tubular member is flared from the neck portion to the distal end of the tubular member to define an enlarged funnel-like opening.	<p>The subject matter is shown in Figure 8. Figures 9b-9e, 9g and 9i, and the descriptive disclosure in the specification:</p> <p style="text-align: center;">Fig. 8</p>  <p>"Referring to FIG. 8, an inner sleeve, outer sleeve or singular sleeve balloon protector of the present invention may also be provided in the form of a polymeric tube 60 with flared proximal end 62, flared distal end 64 and a longitudinal slit 37. This inventive balloon protector is unique in that the balloon protector can be removed from the catheter after the catheter has been prepped and loaded onto a guide wire. This allows the balloon protector to be peeled off the shaft, like peeling a banana. Such a construction allows a doctor to prep and introduce the guide wire into the catheter without touching the balloon."</p> <p style="text-align: right;">(page 11, lines 16-23)</p>	<p>Same as in application 08/812,351. Figures 8, 9b-e, 9g and 9, discussed at left for application 08/812,351, are found in this application. The corresponding disclosure is found at page 13, line 28 - page 15, line 3.</p>	<p>Same as in application 08/812,351. Figures 8, 9b-e, 9g and 9, discussed at left for application 08/812,351, are found in this application. The corresponding disclosure is found at page 13, line 28 - page 15, line 3.</p>	<p>Same as in application 08/812,351. Figures 8, 9b-e, 9g and 9, discussed at left for application 08/812,351, are found in this application. The corresponding disclosure is found at page 13, line 28 - page 15, line 3.</p>

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Fig. 9b*Fig. 9c**Fig. 9d**Fig. 9e**Fig. 9g**Fig. 9i*

"A balloon protector according to the present invention may be a spiral sleeve 66 made of a polymeric material or a metal ribbon. It can also be formed by spiral cutting a tube to be the balloon protector, in a configuration as shown in FIGS. 9a-h and j and as shown at FIGS. 4a-b.

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	<p>This balloon protector conforms to diameter changes throughout the length of the collapsed balloon, and in a preferred embodiment has a pre-mounted inner diameter which is less than the outer diameter of the collapsed balloon to provide radial compression when applied on the balloon. The radial strength of the spiral sleeve is related to the material of which the sleeve is made, the pitch of the spiral, the wall thickness of the sleeve and the inner diameter of the sleeve. A preferred material for this balloon protector is LDPE. The spiral sleeve provides a device with a compressive force that has flexibility to conform to diameter changes of a collapsed balloon (a balloon which when expanded has a non-uniform diameter). The spiral sleeve 66 may be used alone as a single balloon protector, or as an inner sleeve with any suitable outer sleeve, for example, a sleeve with a longitudinal slit as shown at FIGS. 3 and 8.</p> <p>The spiral sleeve 66 may also be used as an outer sleeve with any suitable inner sleeve, for example, a sleeve with a longitudinal slit as shown at FIGS. 3 and 8.</p> <p>FIGS. 9a-h and j show alternative embodiments of a spiral sleeve according to the present invention. FIG. 9a and 9b show a spiral sleeve with a flare at one end, FIG. 9a showing a spiral sleeve with a proximal flare 48, and FIG. 9b showing a distal flare 49. FIG. 9c shows a spiral sleeve 66 with proximal and distal flares 48, 49. Prior to use (in a pre-mounted state) the spiral sleeves shown in FIGS. 9a-c have a substantially uniform outer diameter, inner diameter and wall thickness. FIG. 9d shows a spiral sleeve with proximal and distal flares 48, 49. FIG. 9e shows a spiral sleeve with a distal</p>		
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<p>2 A protective sleeve as defined in claim 1 further comprising: an outer sleeve disposed about those portions of the tubular member proximal of the flared distal portion, the outer sleeve being configured to maintain the slit of the tubular member in a closed configuration.</p>	<p>flare. FIG. 9f shows a spiral sleeve with a proximal flare. Prior to use (in a premounted state) the spiral sleeves shown in FIGS. 9d-f have a substantially uniform outer diameter, a non-uniform, tapered inner diameter and a non-uniform wall thickness. FIG. 9g shows a spiral sleeve with proximal and distal flares 48, 49. FIG. 9h shows a spiral sleeve with a proximal flare 48. FIG. 9j shows a spiral sleeve with a distal flare 49. Prior to use (in a premounted state) FIGS. 9g, h and j have a non-uniform tapered inner and outer diameter, and a substantially uniform wall thickness." (page 11, line 24-page 12, line 22)</p>			
<p>Figures 2 and 5 show inner and outer sleeves. See also page 9, lines 26-30. Fig. 8, is disclosed as "an inner sleeve, outer sleeve or singular sleeve balloon protector of the present invention" at page 11, lines 16-17. Page 3, lines 15-18 "The second removable (outer) sleeve is positioned over the first (inner) sleeve, the outer sleeve having a constrictive relationship with the inner sleeve. The outer sleeve thereby provides an additional compressive force to reduce the profile of the constricted balloon." Page 13, lines 24-29: "Prior to placement of sleeves 28 and 40 on the catheter, outer sleeve 40 has an inner diameter less than the outer diameter of the inner sleeve 28. In a preferred embodiment, the inner diameter of outer protector sleeve 40 slightly smaller (about 0.001 inch smaller, for example) than the outer diameter of inner protector sleeve 28. This causes slit 36 to be closed when outer protector sleeve 40 is applied over inner protector sleeve</p>		<p>Same figures and disclosure as in application 08/812,351. Corresponding disclosure for page 11, lines 16-17 of application 08/812,351 is found at page 12, lines 7-11. Corresponding disclosure for page 3, lines 15-18 of application 08/812,351 is found at page 3, lines 22-25. Corresponding disclosure for page 13, lines 24-29 of application 08/812,351 is found at page 16, lines 5-10.</p>	<p>Same figures and disclosure as in application 08/812,351. Corresponding disclosure for page 11, lines 16-17 of application 08/812,351 is found at page 12, lines 7-11. Corresponding disclosure for page 3, lines 15-18 of application 08/812,351 is found at page 3, lines 22-25. Corresponding disclosure for page 13, lines 24-29 of application 08/812,351 is found at page 16, lines 5-10.</p>	<p>Same figures and disclosure as in application 08/812,351. Corresponding disclosure for page 11, lines 16-17 of application 08/812,351 is found at page 12, lines 7-11. Corresponding disclosure for page 3, lines 15-18 of application 08/812,351 is found at page 3, lines 22-25. Corresponding disclosure for page 13, lines 24-29 of application 08/812,351 is found at page 16, lines 5-10.</p>

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	28, in addition to overall compression of inner protective sleeve 28."			
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